ISO TC184/SC4 N1110 (QC N171)
(Supercedes QC N146)

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ISO TC 184/SC4 QUALITY COMMITTEE DOCUMENT

Technical Committee 184 for Industrial Automation Systems and Integration
Subcommittee 4 for Industrial Data

SC4 Quality Manual

ISO TC 184/SC4 Quality Committee
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This document can be downloaded as a ZIP archive containing all the constituent HTML files and GIF images, or as a single printable PDF file.

Contents

Readers should note that this document includes references to other SC4 standing documents that are either not yet approved or are subject to revision. Every effort will be made to ensure that this document is updated as other standing documents are approved are revised; however, readers are encouraged to seek the latest versions of documents referenced here.

Acknowledgements

Allison Barnard Feeney (NIST) and Jesse Crusey (NIST) developed the initial structure and content of this quality manual. Members of the Quality Committee produced a revised structure for the document at a workshop held at NIST in March 1999. Allison Barnard Feeney edited a partial draft reflecting the revised structure. Julian Fowler (PDT Solutions) edited and Tom Warren (Oklahoma State University) performed an editorial review of the version (QC N121) circulated for SC4 Standing Document Ballot. Members of the Quality Committee reviewed and resolved the issues raised during the ballot at a workshop held in Long Beach CA in September 1999. Julian Fowler edited and Tom Warren performed an editorial review a draft version (QC N146) for final review by QC and Working Group conveners. Julian Fowler edited this version for publication as an SC4 Standing Document

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1 Introduction

ISO TC184/SC4 aims to produce standards of high and consistent quality. In particular, the following quality goals apply to the work of SC4:

- each SC4 standard shall be complete;
- each SC4 standard shall be fully comprehensible to those who review the technical content of the standard, implement the standard in software products, test implementations of the standard, and deploy standards-based software products in industry;
- each SC4 standard shall be developed, reviewed, approved, and published within the timescales laid down by ISO Technical Management Board and by SC4;
- each SC4 standard shall conform to ISO and SC4-approved directives for the structure and content of standards;
- each SC4 standard shall conform to ISO and SC4-approved directives for presenting standards.

SC4 has established a Quality Committee to document and monitor a quality system that supports these goals. This quality manual is the cornerstone of the SC4 quality system and defines the specifications, quality assessment criteria, and approval procedures that support built-in quality for all SC4 standards. All SC4 project teams shall use this manual as a guide for developing standards.

NOTE In this document "SC4 standard" refers to any of the standards deliverables of the approved ISO projects assigned to SC4. This manual also applies to deliverables that are published as Publicly Available Specifications (PAS), Technical Specifications (TS), or Technical Reports (TR). Where it is necessary to refer to a part (of a multi-part standard), the manual uses "SC4 part".

1.1 Objectives

The objectives of the SC4 Quality Manual are as follows:

- to provide SC4 projects with a stable document that enumerates the specifications, quality assessment criteria, and approval processes that they should use to achieve quality standards;
- to define methods and metrics that help to ensure that SC4 project teams perform their tasks to consistently high levels of quality;
- to provide a foundation for improving quality practices within SC4;
- to provide objective evidence for determining and correcting the causes of poor quality.

1.2 Quality management versus quality assurance

Lack of quality in a proposed standard impedes adequate technical review, increases the likelihood for misunderstanding, and causes delays in adopting the standard. SC4 projects focus attention on quality in two places:

- the processes, procedures, tools, and techniques that ensure quality in the developing standards;
- inspecting the draft standard at specific points during its development.

Each SC4 project applies quality management through accepted development methods, procedures, and

assessments designed to achieve quality in the product as the team develops it. The project team performs quality assurance through in-process or post-production inspections that are performed with a different set of procedures. Quality assurance procedures only address evaluating the characteristics of a standard, as opposed to all aspects of developing the standard.

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2 Scope

This standing document includes specifications, quality assessment criteria, and approval procedures for developing all SC4 standards. These standards include the following:

- ISO 10303 Product data representation and exchange;
- ISO 13584 Parts library;
- ISO 15531 Manufacturing management data;
- ISO 15926 Integration of life-cycle data for process plants including oil and gas production facilities;
- ISO 18876 Integration of industrial data for exchange, access, and sharing.

This standing document defines the responsibilities for quality within SC4. These responsibilities are assigned to the following:

- SC4;
- the SC4 Chair and Secretariat;
- Working Group conveners;
- the SC4 Policy and Planning Committee (PPC);
- the SC4 Change Management Committee;
- project leaders;
- part editors;
- project team members;
- the SC4 Quality Committee.

This standing document specifies the elements required to assess and improve the quality of an SC4 part.

The following are within the scope of this standing document:

- assignment of responsibilities in areas such as quality reviews, training, and tool selection and use;
- specifications for developing the various portions of SC4 standards and different types of SC4 parts;
- quality assessment criteria applied by SC4 project teams to verify the technical quality of a standard;

EXAMPLE 1 Technical quality criteria include the relevance, clarity, and utility of the specifications documented in a standard. These criteria determine whether the specification can be be unambiguously and economically implemented.

- quality assessment criteria applied by SC4 project teams to verify the document quality of a standard;

EXAMPLE 2 Document quality criteria include the format and structure of the part document and the clarity of definitions, examples, graphical models, and illustrations.

- procedures for reviewing and approving SC4 standards.

The following are within the scope of the SC4 quality system, but are documented in other standing documents and Quality Committee documents that this quality manual references:

- the overall procedures for developing and approving SC4 standards;
- assessment criteria for evaluating the accuracy of the technical content of a part;
- definition of requirements that SC4 standards shall meet;

NOTE The requirements for parts derive from documents approved by SC4. Clause 5 below lists the primary references that contain these requirements.

- checklists for reviewing different types of SC4 standard and SC4 part;
- the procedures used for developing, documenting and approving SC4 parts, including those for ISO 10303 resource integration and application interpretation.

The other documents within the SC4 quality system are listed in this document's bibliography. A maintained listing of methods documents, guidelines, and other relevant materials for standards developers is maintained at http://www.nist.gov/sc4/www/necsdocs.htm.

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3 Terms, definitions, and abbreviations

3.1 Terms defined in ISO 10303-1

For the purposes of this standing document, the following terms defined in ISO 10303-1 apply:

- abstract test suite (ATS);
- application activity model (AAM);
- application interpreted model (AIM);
- application protocol (AP);
- application reference model (ARM);
- integrated resource (IR).

3.2 Terms defined in ISO 10303-202

For the purposes of this standing document, the following term defined in ISO 10303-202 applies:

- application interpreted construct (AIC).

3.3 Terms defined in ISO 8402

For the purposes of this standing document, the following terms defined in ISO 8402 (repeated below for convenience) apply:

NOTE The definitions below are repeated verbatim from ISO 8402. The notes provided with some of the definitions are added or adapted from ISO 8402 for the purposes of the SC4 Quality Manual.

3.3.1
conformity
fulfilment of specified requirements

NOTE The above definition is valid for the purposes of quality standards. ISO/IEC Guide 2 defines the term "conformity" differently.

3.3.2
corrective action
action taken to eliminate the causes of an existing nonconformity (3.3.4), defect (3.4.1), or other undesirable situation in order to prevent recurrence

NOTE The corrective actions may involve changes in procedures (3.3.6) to achieve requirements for quality (3.4.4).

3.3.3
management review
formal evaluation by top management of the status and adequacy of the quality system (3.3.9) in relation to quality policy (3.3.8) and objectives

NOTE 1 Management review may include review of the quality policy.

NOTE 2 Quality audit (3.4.6) results are one of the possible inputs to management review.

3.3.4
nonconformity
nonfulfilment of a specified requirement

3.3.5
preventive action
action taken to eliminate the causes of a potential nonconformity (3.3.4), defect (3.4.1), or other undesirable situation in order to prevent occurrence

NOTE The preventive actions may involve changes in procedures (3.3.6) to achieve requirements for quality (3.4.4).

3.3.6
procedure
specified way to perform an activity

NOTE 1 In many cases, procedures are documented (for example, quality system (3.3.9) procedures).

NOTE 2 If a procedure is documented, "written procedure" or "documented procedure" is frequently used.

3.3.7
quality control
operational techniques and activities that are used to fulfil requirements for quality (3.4.4)

NOTE 1 Quality control involves operational techniques and activities aimed both at monitoring the development of the SC4 part and at eliminating causes of unsatisfactory documentation at all stages of the SC4 part, through International Standard approval, in order to achieve economic effectiveness.

NOTE 2 Some quality control and quality assurance (3.4.5) actions are interrelated.

3.3.8
quality policy
overall intentions and direction of an organization with regard to quality (3.4.4) as formally expressed by top management

NOTE The quality policy forms one element of the corporate policy and is authorized by top management.

3.3.9
quality system
organizational structure, procedures (3.3.6), processes, and resources needed to implement quality management

NOTE 1 The organizational structure of the quality system will identify responsibilities, authorities, and relationships, arranged in a pattern, through which an organization performs its functions.

NOTE 2 The quality system should be as comprehensive as needed, to meet the quality (3.4.4) objectives.

3.3.10
specification
document stating requirements

NOTE A specification should refer to other relevant documents and indicate the means and the criteria whereby conformity (3.3.1) can be checked.

3.4 Terms defined in the Guidelines for the content of application protocols using application modules

For the purposes of this standing document, the following term defined in the Guidelines for the content of application protocols using application modules (repeated below for convenience) applies:

NOTE This definition and its source are subject to change, as the referenced document has not yet been approved as an SC4 standing document.

3.4.1
application module
a reusable collection of scope statement, information requirements, mappings and module interpreted model that supports a specific usage of product data across multiple application contexts

3.5 Other terms and definitions

For the purposes of this Standing Document, the following terms and definitions apply.

3.5.1
defect
nonfulfilment of an intended usage requirement or reasonable expectation of any feature of an SC4 standard

NOTE 1 This definition is adapted from that specified in ISO 8402.

NOTE 2 Defects can result from nonconformity to the specifications contained in or referenced by this SC4 Quality Manual.

3.5.2
design review
documented, comprehensive, and systematic examination of an SC4 standard to evaluate its capability to fulfil the requirements for quality, identify problems, if any, and propose the development of solutions

NOTE This definition is adapted from that specified in ISO 8402.

3.5.3
peer review
assessment of the capabilities of an individual or group of people conducted by others with a similar professional or technical background, skills, and experience

3.5.4
quality
meeting agreed customer requirements; the totality of features and characteristics of a product or service that bears upon its ability to satisfy stated or implied needs.

NOTE This definition is adapted from that specified in ISO 8402.

3.5.5
quality assurance
all the planned and systematic activities implemented with the quality system (3.3.9) and demonstrated as needed to provide adequate confidence that the product or service will fulfil the requirements for quality (3.5.4)

NOTE 1 There are both internal and external purposes for quality assurance:

- internal quality assurance provides confidence to SC4;
- external quality assurance provides confidence to the user of SC4 standards.

NOTE 2 Some quality controls (3.3.7) and quality assurance (3.5.5) actions are interrelated.

NOTE 3 Unless requirements for quality (3.5.4) fully reflect the needs of the user, quality assurance may not provide adequate confidence.

NOTE 4 This definition is adapted from that specified in ISO 8402.

3.5.6
quality audit
systematic and independent examination to determine whether quality (3.5.4) activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve the quality objectives

NOTE 1 Quality audits are carried out by staff working in cooperation with relevant personnel but not having direct responsibility in the areas being audited.

NOTE 2 One purpose of a quality audit is to evaluate the need for improvement or corrective action (3.3.2). An audit should not be confused with routine quality reviews within a Project.

NOTE 3 Quality audits can be conducted for internal or external purposes.

NOTE 4 This definition is adapted from that specified in ISO 8402.

3.5.7
quality audit observation
statement of fact made during a quality audit (3.5.6) and substantiated by information that can be proved true, based on facts obtained through observation, test, or other means

NOTE This definition is adapted from that specified in ISO 8402.

3.5.8
quality auditor
person experienced in using SC4 standing documents, their stated requirements, and ISO standards requirements to perform quality audits (3.5.6)

NOTE This definition is adapted from that specified in ISO 8402.

3.5.9
quality management
all activities of management that determine the quality policy (3.3.8), objectives and responsibilities, and implement them by means of a quality plan (3.5.11), quality control (3.3.7), and quality assurance (3.5.5) within a quality system (3.3.9)

NOTE 1 Quality management is the responsibility of all levels of management but must be led by top management. Its implementation involves all members of ISO TC 184/SC4.

NOTE 2 In quality management, consideration is given to economic aspects and the usefulness of the ISO TC 184/SC4 standards.

NOTE 3 This definition is adapted from that specified in ISO 8402.

3.5.10
quality manual
document stating the quality policy (3.3.8) and describing the quality system (3.3.9) for ISO TC 184/SC4

NOTE 1 A quality manual may relate to the totality of an organization's activities or only to a part of it. The title and scope of the manual reflects the field of application.

NOTE 2 A quality manual will contain the following as a minimum:

- quality policy (3.3.8);
- the responsibilities, authorities, and interrelationships of personnel who manage, perform, verify, or review work affecting quality (3.5.4);
- the quality system (3.3.9), procedures (3.3.6), and instructions;
- a statement for reviewing, updating, and controlling the quality manual.

NOTE 3 This definition is adapted from that specified in ISO 8402.

3.5.11
quality plan
document setting out the specific quality (3.3.8) practices, resources, and sequence of activities relevant to ISO TC 184/SC4 projects that develop International Standards

NOTE 1 A quality plan usually makes reference to the portion of the quality manual (3.5.10) applicable to specific classes of SC4 parts.

NOTE 2 This definition is adapted from that specified in ISO 8402.

3.5.12
validation

confirmation by examination and provision of information that can be proved true, based on facts obtained through observation or test that the particular requirements for a specific intended use are fulfilled

NOTE 1 In design and development, validation examines the product to determine conformity (3.3.1) with user needs.

NOTE 2 Validation is normally performed on the final product under defined conditions. It may be necessary in earlier stages.

NOTE 3 Multiple validations may be carried out if there are different intended uses.

NOTE 4 Project Teams validate SC4 standards as part of the development process. P-members, A-liaisons, and other interested bodies validate SC4 standards through trial implementations and reviews associated with the ISO ballot processes. Industry validates SC4 standards through implementation and use. Any errors in a published SC4 standard that are detected during industry validation can be reported and corrected through the SEDS process.

NOTE 5 This definition is adapted from that specified in ISO 8402.

3.5.13
verification
confirmation by examining and providing information that can be proved true, based on facts obtained through observation or test that specified requirements have been fulfilled

NOTE 1 In design and development, verification concerns the process of examining the results of a given activity to determine conformity (3.3.1) with the stated requirements for that activity.

NOTE 2 This definition is adapted from that specified in ISO 8402.

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4 Management responsibility

4.1 Quality policy statement

It is SC4's policy to develop standards to a high and consistent level of quality, and to achieve quality by executing the appropriate procedures within projects. Quality of SC4 standards is measured by accurate satisfaction of industry requirements, implementation and deployment of standards in commercial software systems, and approval of standards through the ISO process without the need for rework or reballoting.

This policy is supported by a quality system that is described in this manual. The SC4 quality system is an implementation of ISO 9001 appropriate to the needs and capabilities of a voluntary standards organization. The quality system consists of procedures, guidelines, and work instructions that supplement the ISO Directives, provides information that directs and guides the work of SC4 projects, and defines metrics for assessing the quality of SC4 standards.

Project teams are responsible for the quality of their deliverables.

4.2 Organization

SC4 is responsible for implementing the SC4 quality policy.

Project leaders of SC4 projects are responsible for ensuring that their products satisfy the requirements of the SC4 Quality Manual.

All members of SC4 project teams shall be familiar with the contents of the SC4 Quality Manual and shall comply with the policies and procedures specified in it and other documents referenced by it. Project teams are responsible for providing feedback to the Quality Committee for improvements to the review process, approval checklists, methods documents, and training materials.

Project teams provide resources to the Quality Committee to support continuous maintenance and improvement of the SC4 quality system and its components.

The Quality Committee maintains the quality system and its components, providing training and advice on quality issues to SC4 and to project teams, and performing audits of projects against quality requirements.

The P-members and A-liaisons of SC4 are responsible for nominating suitably qualified and experienced experts to the Quality Committee.

4.3 Management review

The Quality Committee, the Working Group conveners, the Policy and Planning Committee, and the Change Management Committee shall jointly conduct an annual review of SC4's quality performance.

This review shall include consideration of the following:

- success of projects in meeting ISO and SC4 schedule requirements;
- success of projects in meeting quality metrics;
- requirements for mandatory audits;
- requirements and opportunities for process improvement.

The SC4 Chair shall report the results of this review to SC4.

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5 Quality system

The SC4 quality system includes the SC4 Quality Manual (this document), checklists for approval of SC4 parts by project leaders and conveners, quality assessment criteria for use in project reviews, and approved SC4 methods documents that provide requirements on technical and editorial development of SC4 standards.

5.1 General

Whether SC4 standards developers use quality assessment criteria as a development aid or as a quality inspection tool, they shall fulfil the requirements for approval of SC4 standards specified in this quality manual. The value of the quality system within SC4 depends upon the following:

- the existence, acceptance, and dissemination of quality requirements for standards development;
- the existence, acceptance, and dissemination of quality requirements for standards;
- the understanding, practical application, and consistent use of these quality requirements by project teams.

5.2 Review and approval procedures

Figure 1 below shows an overview of the review and approval process that takes place before each ballot

cycle. The review process is described in detail in 5.3.2 below. The approval process is described in detail in 5.3.3 below.

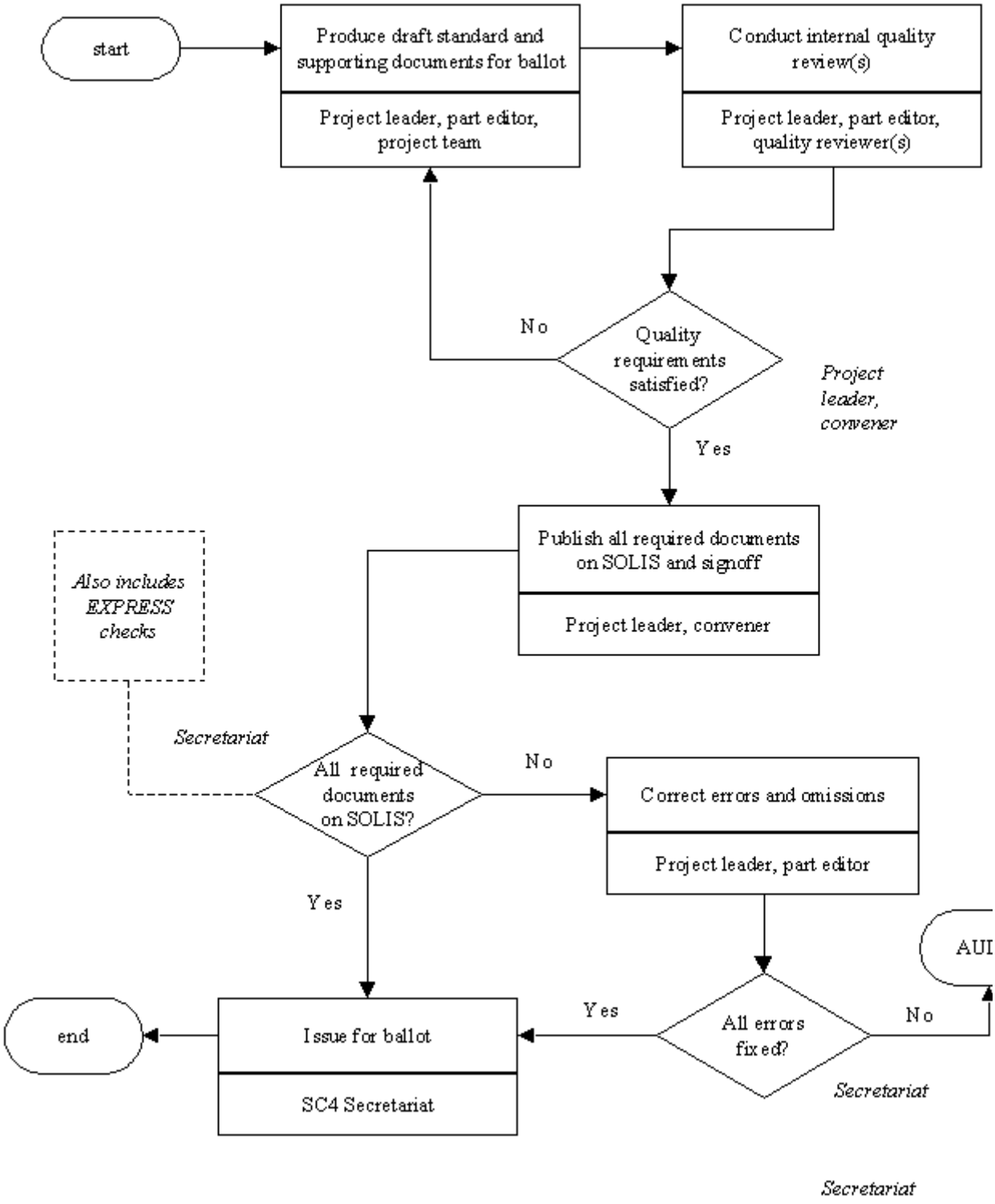

Figure 1 - Review and approval procedure

Project teams and working groups are responsible for the following:

- part quality;
- coordinating and conducting part reviews;
- documenting review processes used, issues raised, resolution of issues, deferment of issues, and quality methods used.

Project teams are responsible for following SC4-approved methods documents when developing their parts and for conducting internal reviews at appropriate points during part development.

Project leaders shall conduct part reviews prior to publication and shall sign-off that parts are of acceptably high quality for release.

Conveners shall conduct part reviews following the Project Leader sign-off and shall sign-off that parts are of acceptably high quality for release.

The Quality Committee conducts audits if a project team team fails to fulfil the quality requirements that apply to it. An audit focuses on the methods and procedures used by the project team. An audit does not normally include detailed review and correction of part documents.

NOTE See clause 9 of this document for details of the audit process. The Quality Committee may also conduct audits of projects in the context of quality and process improvement activities.

5.3 Specifications, review criteria, and approval

Each SC4 part class contains categories of material that are governed by different specifications and are subject to different evaluations. Some categories of material such as the scope, normative references, and definitions apply to all parts. Some categories of material such as application reference models apply to only one class of parts. SC4 parts are divided into the following classes:

- text parts;
- languages;
- implementation methods;
- general data model parts;
- intergrated resources;
- application protocols;
- abstract test suites;
- application interpreted constructs;
- application modules;
- view exchange protocols.

Procedures and guidelines for developing and documenting particular classes of parts are found in the various SC4 standing documents referenced in the class-specific clauses of this quality manual.

Project teams shall use these standing documents to develop parts to a high level of quality. The Quality Committee uses the same standing documents to derive the quality assessment criteria that evaluate SC4 parts. Procedures for modifying and approving standing documents are specified in the SC4 Organization Handbook.

5.3.1 Specifications

Table 1 below summarizes the specifications that apply to each class of SC4 part.

Table 1 - Specifications

	text	language	impl. method	gen. data model	IR	AP	ATS	AIC	AM	VEP
COED	*	*	*	*	*	*	*	*	*	*
IDP3	*	*	*	*	*	*	*	*	*	*
SDs	**	**	**	**	*	*	*	*	*	**
Formal syntax		*	***							
EXPRESS		***	***	*	*	*		*	*	***
Part 21		***	***					***		***

ATS Guidelines						*	*	***		
Programming language			***							
Syntactic & semantic rules				***	*					
Terminology						*				
AP Guidelines						*				
AIM Guidelines						*		*	*	
Interpretation procedures						*		*	*	
AM Usage Guidelines						****				
Modular AP Content Guidelines						****				
MT Guidelines						*		*	*	
Part 31						*	*			
IDEF0						*				
IDEF1X						***				
Part 32							*			
EXPRESS-I							***	***		
Part 22							***			
AIC Guidelines								*		
AM Guidelines									*	

In this table, abbreviations and symbols have the following meanings:

Column headings:

text:
: text parts (see 5.3.4);

language:
: langugage definition parts (see 5.3.5);

impl. method:
: implementation methods (see 5.3.6);

gen. data model:
: general data model parts (see 5.3.7);

IR:
: integrated resources (see 5.3.8);

AP:
: application protocols (see 5.3.9);

ATS:
: abstract test suites (see 5.3.10);

AIC:
: application interpreted constructs (see 5.3.11);

AM:
: application modules (see 5.3.12);

NOTE 1 See clause 5.3.12 below for information about the status of methods that apply to developing application modules.

VEP:
view exchange protocols (see 5.3.13).

Row headings:

The project team shall have access to, be familiar with, understand, and apply the following:

COED:
the Concise Oxford Dictionary of Current English.
IDP3:
the ISO/IEC Directives, Part 3.
SDs:
the Supplementary directives for the drafting and presentation of ISO 10303.

NOTE 2 Although ISO 10303 parts form the main focus of the Supplementary Directives, this document contains provisions which apply to other SC4 parts.

EXAMPLE 1 The requirements for wording of the Foreword, as specified by ISO Central Secretariat and documented in the Supplementary Directives, apply to all SC4 parts.

EXAMPLE 2 The conventions for documentation of EXPRESS schemas may be applied to general data model parts.

Formal syntax:
any formal syntax notation used as specified in the part by normative or informative reference.
EXPRESS:
ISO 10303-11: Description methods: The EXPRESS language reference manual.
Part 21:
ISO 10303-21: Implementation methods: Clear text encoding of the exchange structure.
ATS Guidelines:
the Guidelines for the development of abstract test suites.

NOTE 3 At the time of publication of this quality manual, a second edition of these Guidelines is being prepared for publication as an SC4 standing document. Project teams, particularly those who have not yet submitted their part for Committee Draft ballot, should be prepared to apply the specifications contained in the second edition.

Programming language:
any programming language used, specified in the part by normative or informative reference.
Syntactic & semantic rules:
STEP (Standard for the Exchange of Product Model Data) Resource Integration: Semantic & Syntactic Rules.

NOTE 4 Each project team developing a general data model part that is to be considered as "common resources" should take this specification into consideration as the basis for use of the general data model part by ISO 10303 application protocols.

Terminology:
materials such as terminology standards, dictionaries, or text books that are relevant to the domain of the part.
AP Guidelines:
the Guidelines for the development and approval of STEP application protocols.
AIM Guidelines:
the Guidelines for application interpreted model development.
Interp. Procs.:
the Procedures for application interpretation.

NOTE 5 At the time of publication of this quality manual, the Procedures for application interpretation are not yet complete and have not been approved as an SC4 standing document. Nonetheless, project teams are encouraged to apply the specifications contained in this document.

AM Usage Guidelines:
the Application module development points within the application protocol development process.
Modular AP Content Guidelines:
the Guidelines for the content of application protocols using application modules.

NOTE 6 At the time of publication of this quality manual, the two documents referenced above have not been approved as SC4 standing

documents. Until they are so approved, they should not be used except by those projects that have been authorized by SC4 to apply the modularization approach on an experimental basis.

MT Guidelines:
the Guidelines for the development of mapping tables.

NOTE 7 At the time of publication of this quality manual, a second edition of these Guidelines (retitled "Guidelines for the development of mapping specifications") is being prepared for publication as an SC4 standing document. Project teams, particularly those who have not yet submitted their part for Committee Draft ballot, should be prepared to apply the specifications contained in the second edition.

Part 31:
ISO 10303-31: Conformance testing methodology and framework: General concepts.
IDEF0:
IEEE Std 1320.1-1998, Standard for Functional Modeling Language - Syntax and Semantics for IDEF0..
IDEF1X:
IEEE Std 1320.2-1998, Standard for Conceptual Modeling Language - Syntax and Semantics for IDEF1X.
Part 32:
ISO 10303-32: Conformance testing methodology and framework: Requirements on testing laboratories and clients.
EXPRESS-I:
ISO/TR 10303-12: Description methods: The EXPRESS-I language reference manual.
Part 22:
ISO 10303-22: Implementation methods: Standard data access interface specification.
AIC Guidelines:
the Guidelines for application interpreted construct development.
AM Guidelines:
the Guidelines for the content of application modules.

NOTE 8 At the time of publication of this quality manual, the document referenced above has not been approved as an SC4 standing document. Until it is so approved, it should not be used except by those projects that have been authorized by SC4 to apply the modularization approach on an experimental basis.

Table cells:

*:
Mandatory specification
**:
Mandatory specification for ISO 10303 parts. Project teams developing other SC4 parts shall apply the provisions of this specification that relate to ISO or SC4 requirements, and are encouraged to apply this specification elsewhere.
***:
Mandatory if the part includes content relevant to the stated specification.
****:
Mandatory for ISO 10303 application protocols that are developed using modules

5.3.2 Review criteria

The quality assessment criteria for evaluating each class of part are documented in the Procedures for Internal Review. These procedures will be continuously improved through feedback from their users.

Table 2 below summarizes the quality assessment criteria that apply to each class of SC4 part.

Table 2 - Quality Assessment Criteria

	text	language	impl. method	gen. data model	IR	AP	ATS	AIC	AM	VEP
Internal review	*	*	*	*	*	*	*	*	*	*
Formal syntax		*	**							

EXPRESS		**	**	*	*	*		*	*	**
Part 21		**	**			**	**	**		**
Programming language		**								
Semantic validation				*	*	*		*	*	
AP Guidelines Interpretation procedures						*			*	
EXPRESS-I							**	**		

In this table, abbreviations and symbols have the following meanings:

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text parts (see 5.3.4);
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implementation methods (see 5.3.6);
gen. data model:
general data model parts (see 5.3.7);
IR:
integrated resources (see 5.3.8);
AP:
application protocols (see 5.3.9);
ATS:
abstract test suites (see 5.3.10);
AIC:
application interpreted constructs (see 5.3.11);
AM:
application modules (see 5.3.12);

NOTE 1 See clause 5.3.12 below for information about the status of methods that apply to developing application modules.

VEP:
view exchange protocols (see 5.3.13).

Row headings:

Internal review:
The project team shall verify that the document meets the relevant specifications by using the Procedures for Internal Review. The Project Team shall conduct an internal review prior to each ISO ballot stage and shall publish the results of this review as an N-numbered document on SOLIS.

NOTE 2 The operation and use of SOLIS is specified in the Annex H of the SC4 Organization Handbook.

NOTE 3 Project teams are strongly encouraged to carry out additional internal reviews while developing a part, and to retain the results of these reviews as part of the project quality records.

EXAMPLE A Project Team may carry out an internal review on a Working Draft prior to its circulation for industry review. In such circumstances some of the review criteria specified in the Procedures for Internal Review may not be applicable. The Project Team should note any criteria that were not applied during such an internal review.

Formal syntax:
The Ppoject team shall validate the syntax specification using the procedure specified in clause 6.2 of this document.
EXPRESS:
The project team shall validate all EXPRESS schemas specified in the part using the procedure

specified in clause 6.1 of this document.

Part 21:

The project team shall validate all ISO 10303-21 files using the procedure specified in clause 6.3 of this document.

Programming language:

The project team shall validate the programming language statements using the procedure specified in clause 6.4 of this document.

Semantic validation:

The project team is encouraged to perform semantic validation of the EXPRESS schemas specified in the part by developing and documenting trial populations and/or prototype software implementations using representative sample data from the application domain(s) that the schemas are designed to support.

AP Guidelines / Interpretation procedures:

The project team shall validate the technical content of the application protocol using the procedures and processes specified for this purpose in the Guidelines for the development and approval of STEP application protocols and in the Procedures for application interpretation.

NOTE 4 At the time of publication of this quality manual, the Procedures for application interpretation are not yet complete and have not been approved as an SC4 standing document. Nonetheless, project teams are encouraged to apply the review procedures contained in this document.

EXPRESS-I:

The Project Team shall validate ISO/TR 10303-12 files and provide documentation describing the validation methods and tools used, and the results of this validation.

Table cells:

*:

Mandatory review procedure

**:

Mandatory if the part includes content relevant to the stated review procedure.

5.3.3 Approval

The following approval procedure applies to all classes of SC4 parts.

The project leader shall verify that the document meets the above specifications by using the Project Leader Approval Checklist for SC4. The project leader shall review the document prior to each ISO ballot stage and shall publish the results of this review as an N-numbered document on SOLIS.

The convener of the Working Group to which the project is assigned shall verify that the document meets the above specifications using the Convener Approval Checklist for SC4. The Convener shall review the document prior to each ISO ballot stage and shall publish the results of this review as an N-numbered document on SOLIS.

5.3.4 Text parts

Text parts include part 1 and the 30-series parts of ISO 10303, parts 1 and 10 of ISO 13584, parts 21, 31, and 41 of ISO 15531, and parts 1 and 3 of ISO 15926.

5.3.4.1 Specifications

The specifications that apply to developing text parts are identified in the column labelled "text" in Table 1 above.

NOTE There are no specific methods documents that apply to text parts. If any specific methods are identified by the Quality Committee or by Project Teams, the methods will be referenced here.

5.3.4.2 Review criteria

The project team shall verify that the document meets the above specifications by using the review procedures identified in the column labelled "text" in Table 2 above.

5.3.5 Language parts

Language parts include ISO 10303-11, the EXPRESS language reference manual.

5.3.5.1 Specifications

The specifications that apply to developing language parts are identified in the column labelled "language" in Table 1 above.

5.3.5.2 Review criteria

The project team shall verify that the document meets the above specifications by using the review procedures identified in the column labelled "language" in Table 2 above.

5.3.6 Implementation methods

Implementation methods include the 20-series parts of ISO 10303.

5.3.6.1 Specifications

The specifications that apply to developing implementation methods are identified in the column labelled "impl. method" in Table 1 above.

5.3.6.2 Review criteria

The project team shall verify that the document meets the above specifications by using the review procedures identified in the column labelled "impl. method" in Table 2 above.

5.3.7 General data models

General data model parts include the 20-series parts of ISO 13584, the 40-series parts of ISO 15531, and ISO 15926-2.

5.3.7.1 Specifications

The specifications that apply to developing general data models are identified in the column labelled "general data model" in Table 1 above.

5.3.7.2 Review criteria

The project team shall verify that the document meets the above specifications by using the review procedures identified in the column labelled "general data model" in Table 2 above.

5.3.8 Integrated resources

Integrated resources include the 40- and 100-series parts of ISO 10303.

5.3.8.1 Specifications

The specifications that apply to developing integrated resources are identified in the column labelled "IR" in Table 1 above.

5.3.8.2 Review criteria

The project team shall verify that the document meets the above specifications by using the review procedures identified in the column labelled "IR" in Table 2 above.

5.3.9 Application protocols

Application protocols are the 200-series parts of ISO 10303.

5.3.9.1 Specifications

The specifications that apply to developing application protocols are identified in the column labelled "AP" in Table 1 above.

5.3.9.2 Review criteria

The project team shall verify that the document meets the above specifications by using the review procedures identified in the column labelled "AP" in Table 2 above.

5.3.10 Abstract test suites

Abstract test suites are the 300-series parts of ISO 10303.

5.3.10.1 Specifications

The specifications that apply to developing abstract test suites are identified in the column labelled "ATS" in Table 1 above.

5.3.10.2 Review criteria

The project team shall verify that the document meets the above specifications by using the review procedures identified in the column labelled "ATS" in Table 2 above.

5.3.11 Application interpreted constructs

Application interpreted constructs are the 500-series parts of ISO 10303.

5.3.11.1 Specifications

The specifications that apply to developing application interpreted constructs are identified in the column labelled "AIC" in Table 1 above.

5.3.11.2 Review criteria

The project team shall verify that the document meets the above specifications by using the review procedures identified in the column labelled "AIC" in Table 2 above.

5.3.12 Application modules

Application modules are the 1000-series parts of ISO 10303.

NOTE 1 The WG10 preliminary work item on STEP modularization is developing detailed methods and guidelines for developing application modules. As soon as these guidelines are completed and approved by SC4, they will be referenced by this quality manual, and the columns labelled "AM" in Table 1 and Table 2 will be completed. Until that time, developers of application modules should to use and review the draft module guidelines available from http://wg10step.aticorp.org/.

NOTE 2 Similarly, The WG10 preliminary work item on STEP modularization will generate changes and/or additions to the specifications and procedures for developing and reviewing ISO 10303 application protocols.

5.3.13 View exchange protocols

View exchange protocols include the 100-series parts of ISO 13584.

5.3.13.1 Specifications

The specifications that apply to developing view exchange protocols are identified in the column labelled "VEP" in Table 1 above.

NOTE There are no specific methods documents that apply to view exchange protocol parts. If any specific methods are identified by the Quality Committee or by Project Teams, the methods will referenced here.

5.3.13.2 Review criteria

The project team shall verify that the document meets the above specifications by using the review procedures identified in the column labelled "VEP" in Table 2 above.

5.4 Planning

In order to satisfy all requirements for quality, each SC4 project shall prepare and implement a quality plan, ensure that the project leader, part editor, and other project team members have the necessary skills to produce a standard, conduct periodic verification of the contents of the standard during its development, and maintain appropriate quality records.

5.4.1 Quality plan

In order to satisfy all requirements for quality, each SC4 project shall prepare and maintain a quality plan as part of its overall project management and planning activities. These activities shall ensure that the project delivers a complete, useful, and high quality standard within timescales that are acceptable to users and implementers in industry, and conform to scheduling requirements defined by the ISO TMB and by SC4.

A quality plan identifies the following:

- tasks and activities that contribute to the quality of the part being developed by the project;
- allocation of resources to quality tasks;
- requirements for training to be undertaken by project members;
- validation/verification actions to be taken before or at particular milestone in the development of the part;
- procedures for maintaining records of quality tasks.

SC4 recommends that each project allocates 10% of its resources to quality-related tasks in order to ensure that all its deliverables are of a high and consistent level of quality, and do not require substantial rework as they move through ballot review and approval. Projects are encouraged to support maintenance and improvement of the SC4 quality system by allocating resources to specific Quality Committee tasks.

The quality plan is part of the project documentation and may be subject to audit.

NOTE A template for creating a quality plan is provided in Annex A of this document.

The proposers of a New Work Item Proposal (NWIP) shall prepare a quality plan and include it as part of the documentation supporting the NWIP. The convener of the Working Group to which the project is allocated shall review each project's quality plan when the project is approved. The convener shall ensure that the quality plan meets the requirements defined in this quality manual, and may recommend any changes to the quality plan that will improve the efficiency or effectiveness of the project.

This requirement applies to all NWIPs that are submitted after the publication of this quality manual as an SC4 standing document.

5.4.2 Required skills and resources

The different roles within SC4 require varying sets of skills. These skills are documented in the following subclauses.

5.4.2.1 Convener

Skills required:	Familiarity with ISO/IEC Directives (Parts 1 & 3), SC4 Organization Handbook, SC4 Quality Manual, and any SC4-approved methods documents that apply to the type of standard being developed within the working group, such as AP Guidlines or ISO 10303 Supplementary Directives.

Relevant training and/or experience:	ISO and SC4 Procedures, SC4 Quality System

5.4.2.2 Project leader

Skills required:	Project management experience, familiarity with ISO/IEC Directives (Parts 1 and 3), SC4 Organization Handbook, ISO 10303 Supplementary Directives, SC4 Quality Manual, Procedures for Internal Review, and any specific guidelines or procedures that apply to the type of standard being developed.	
Relevant training and/or experience:	For all project leaders:	ISO and SC4 Procedures, SC4 Quality System
	For project leaders of all ISO 10303 parts:	STEP Overview.
	For project leaders of ISO 10303 application protocol parts:	AP Development
	For project leaders of all ISO 13584 parts:	PLIB Overview
	For project leaders of all ISO 15531 parts:	MANDATE Overview
	For project leaders of all ISO 15926 parts:	Oil & Gas Overview

5.4.2.3 Part editor

Skills required:	Highly skilled in written and spoken English. Qualification or experience in technical writing. Skill with the authoring tool selected for use on the project. Familiarity with ISO/IEC Directives Part 3 and the Supplementary Directives for the drafting and presentation of ISO 10303, edition 2.
Relevant training and/or experience:	• Technical writing; • ISO and SC4 documentation requirements.

5.4.2.4 Editorial part reviewer

Skills required:	Highly skilled in written and spoken English. Qualification or experience in technical writing. Familiarity with ISO/IEC Directives Part 3 and the Supplementary Directives for the drafting and presentation of ISO 10303, edition 2.
Relevant training and/or experience:	• Technical writing; • ISO and SC4 documentation requirements.

5.4.2.5 Technical usage part reviewer

Skills required:	Familiarity with domain terminology, qualifications, and experience in the domain covered by the standard. Participation in other standardization efforts in the domain, and/or membership of relevant professional associations may also be useful.
Relevant training and/or experience:	None

NOTE Some SC4 projects have produced "Readers' Guide" documents in association with CD or DIS ballots. Given that these include an element of "how to read a standard", they may be useful as part of basic training for industry reviewers. Without this basic training, reviewers may be daunted by the size, complexity, and/or content of the standard to be reviewed.

5.4.2.6 Technical methods part reviewer

Skills required:	For ISO 10303 application protocols: Experience with IDEF0. Experience with EXPRESS and EXPRESS-G. Knowledge of UOFs in other relevant APs. Knowledge of ATS development procedures to ensure consistency and accuracy of AP and to identify omissions.
Relevant training and/or experience:	QC workshop "Using the ATS process to enhance quality in an AP".

5.4.2.7 Interpreter

For an ISO 10303 application protocol, an interpreter is a person who produces the mapping tables showing how each UOF and application object maps to one or more AIM constructs.

Skills required:	Knowledge of the ISO 10303 integrated resources. Knowledge of UOFs in other APs and their mappings to the integrated resources. Knowledge and experience of interpretation practices.
Relevant training and/or experience:	Interpretation methods and practices

5.4.2.8 Integrator

For an ISO 10303 integrated resource, an integrator is a person who develops and/or restructures proposed extensions to the integrated resources in order to maintain and preserve the structural and semantic integration of the integrated resources. For other common resources an integrator is a person who assesses proposed common resources for overlaps and redundancies with the ISO 10303 integrated resources, in order to develop interpretation practices that ensure consistent usage of the common resource by ISO 10303 application protocols.

Skills required:	Knowledge of the ISO 10303 integration architecture. Knowledge of the ISO 10303 integrated resources and of other SC4 common resources. Knowledge and experience of semantic and syntactic integration practices and of using the EXPRESS language in ISO 10303 integrated resource schemas.
Relevant training and/or experience:	Integration methods and practices.

5.4.3 Verification and validation

The primary verification and validation methods for SC4 standards are the Committee Draft, Draft International Standard, and Final Draft International Standard ballots. Similar ballots are conducted for Publicly Available Specifications, Technical Specifications, Technical Reports, and SC4 standing documents.

These ballots serve as an opportunity for industry representatives (via their national standards bodies) to review, comment on, and approve standards with respect to their completeness, correctness, and utility. These criteria determine whether the standard can be unambiguously and economically implemented.

One of the metrics of the SC4 quality system, as stated in the quality policy (see 4.1), is as follows:

> "... approval of standards through the ISO process without the need for rework or reballoting".

It is therefore important for all SC4 projects to identify and eliminate as many errors, omissions, or other quality defects from their documents prior to the formal balloting process. The review and approval procedures specified in 5.2 and the design control procedures specified in clause 5.5 are intended to assist project teams in meeting this goal.

5.4.4 Quality records

Each SC4 project shall maintain quality records. These quality records shall include the following.

- A list of project participants, including their affiliations and contact details. The list of project participants shall identify all people who play the following roles, at all stages of the project:
  - project leader;
  - part editor;
  - project quality representative;
  - editorial part reviewer;
  - technical usage part reviewer;
  - technical methods part reviewer;
  - interpreter (for ISO 10303 application protocols);
  - integrator (for ISO 10303 integrated resources and other SC4 common resources);
  - any other experts nominated to the project by P-members.
- A project document log identifying all documents created or used by the project. Projects are strongly encouraged to use electronic communications. Any project document that is distributed at a meeting of ISO TC184/SC4 or any of its working groups shall be assigned a WG N-number (see 7.2) and shall be published on SOLIS.
- A project issues log that records all issues against the project's standard(s). The issues log may be subdivided if the project is responsible for more than one standard.

EXAMPLE Many SC4 projects are responsible for an ISO 10303 application protocol and an ISO 10303 abstract test suite. Such a project may chose to maintain separate issues logs for the AP and for the ATS.

- A record of reviews conducted of the standard(s) for which the project is responsible.
- Completed checklists and other documents as required by the review and approval procedures specified in 5.2 and by the design control procedures specified in clause 5.5.

5.5 Maintenance of the quality system

5.5.1 Procedure for approval of checklists

The Quality Committee maintains a page on the SC4 On-Line Information Service (SOLIS) that lists all ISO/IEC Directives, SC4 standing documents, and checklists that apply to SC4 standards development. On the world wide web, go to <http://www.nist.gov/sc4/www/necsdocs.htm>.

All checklist items are supported by requirements in approved standing documents, ISO Directives, or other documents that a project shall adhere to (see 5.3). Each checklist item shall cite the source of the requirement.

The Quality Committee approves checklists for use by SC4 project teams using the following procedure.

- The Quality Committee creates or updates a checklist and publishes a draft on SOLIS.
- The Committee invites comments from QC members, who will have four weeks to respond.

NOTE The Quality Committee encourages all SC4 project leaders and part editors to join the QC email exploder and to participate in reviews of checklists and other components of the SC4 quality system.

- If there are no substantial comments against the draft, it is approved for use.
- Minor editorial changes may be made before publication of the approved version without further review.
- The SC4 Secretariat updates the page on SOLIS, and informs all conveners, project leaders, and part editors of the availability of the new version.

If an error is discovered in a checklists that would result in errors in standards validated using the checklist, the Quality Committee coordinator may recommend that a revised checklist, correcting the error, can be used before the Quality Committee formally approves it.

5.5.2 Issues against checklists

If a project team finds errors or ambiguities in a checklist, or requires clarifications regarding the use of a checklist, the project leader shall send an issue to the QC exploder (qc@cme.nist.gov).

The Quality Committee maintains an issues log for each checklist and publishes it on SOLIS. Any checklist

that has open issue(s) is flagged as such on SOLIS. The Quality Committee coordinator periodically reviews open issues against approved checklists to determine whether work is required to resolve these issues and update the checklist.

5.5.3 Procedure for approval of standing documents

Many of the components of the SC4 quality system (including this quality manual) are approved and published as SC4 standing documents. Procedures for review and approval of standing documents are specified in the SC4 Organization Handbook. The following procedure only applies to standing documents that are part of the SC4 quality system.

EXAMPLE The SC4 Organization Handbook is an SC4 standing document that is not a part of the quality system and is therefore subject to different review, approval, and publication procedures.

Each standing document that is being developed or is subject to revision has a project leader, who a member of the Quality Committee or, if the standing document is being created within another Working Group, a member of that Working Group.

NOTE 1 If a standing document is being created within a Working Group, its project leader should liaise with the QC coordinator to ensure that the work is consistent with the overall quality system.

Before any standing document is balloted by SC4, the project leader publishes a completed draft document on SOLIS with a QC or WG N-number and initiates a four-week review period by sending a message to the relevant WG or QC email exploder.

NOTE 2 If a standing document is being created within a Working Group, the project leader is encouraged to involve members of the QC as well as the WG in this review.

If technical issues are identified during this review, the project leader updates the draft document and republishes it for a further four-week review. If no technical issues are identified, the project leader prepares the document for ballot, taking any editorial issues into consideration. Before the standing document ballot can start, the project leader completes the following actions:

- complete the relevant sections of the project leader checklist for the document and publish the results on SOLIS;
- publish the document on SOLIS with a QC or WG N-number;
- send a message to the sign-off email exploder (signoff@cme.nist.gov) indicating his/her approval of the document.

The QC coordinator (or, if the standing document is being created within a Working Group, the WG convener) then obtains and reviews the draft standing document for approval. If changes are required, the coordinator/convener identifies changes and sends the comments back to the project leader. The project leader then amends the document and republishes it, with a new N-number.

If the coordinator/convener is in concurrence with the document, he/she then completes the following actions:

- Complete the relevant sections of the Convener checklist for the document, and publish the results on SOLIS.
- Send a message to the sign-off email exploder (signoff@cme.nist.gov) indicating his/her approval of the document.

When the SC4 Secretariat obtains a signoff from the coordinator/convener on a standing document, the SC4 Secretary sends the corresponding document to the P-members for standing document ballot.

5.5.4 Issues against standing documents

Issues against standing documents are a subject of the SEDS procedures documented in the SC4 Organization Handbook, and any standing document that has open SEDS issues is flagged as such on SOLIS.

The Quality Committee (in consultation with the SC4 Chair and Secretariat) may recommend that project teams apply a draft standing document before it is formally approved by SC4.

5.5.5 Issues against ISO Directives

If project teams (or any other SC4 personnel) find errors or ambiguities in ISO/IEC Directives Part 1 or ISO/IEC Directives Part 3, or clarifications are required, they shall send an issue to the QC exploder (qc@cme.nist.gov).

The Quality Committee maintains contact with the ISO Central Secretariat in order to raise issues against ISO/IEC Directives Part 1, ISO/IEC Directives Part 3, and other ISO/IEC documents that apply to SC4 standards.

ISO/IEC Directives Parts 1 and 3 are published on SOLIS. If any of the requirements of these Directives are altered (for example, by ISO Technical Management Board resolutions), information about these alterations is provided to project leaders via the appropriate e-mail exploder and/or briefings by the SC4 Secretariat, and is also published on SOLIS.

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6 Design control

6.1 Procedure for validation of EXPRESS models

If a part includes data specifications in EXPRESS, the project team shall validate all EXPRESS schemas specified in the part using at least two EXPRESS tools from different code bases. The project team shall provide a list of the EXPRESS tools used to validate the EXPRESS schemas, and shall provide log files or other documented evidence of successful validation. The project team shall include the results of this validation in a validation report for the part, which shall also identify the tools used to perform the validation. The project team shall append the validation report to the published quality review report(s).

The project team shall apply this procedure to EXPRESS schemas and schema fragments provided as examples and other informative elements, as well as normative schema specifications.

6.2 Procedure for validation of formal syntax specifications

If a part includes a formal syntax specification, the project team shall validate the syntax specification.

EXAMPLE Language parts and implementation methods parts include syntax specifications using formal notations, such as Wirth Syntax Notation (WSN) and Extended Backhaus Naur Form (EBNF).

The project team shall include the results of this validation in a validation report for the part, which shall also identify the tools used to perform the validation. The project team shall append the validation report to the published quality review report(s).

6.3 Procedure for validation of ISO 10303-21 files

If a part includes ISO 10303-21 files, the project team shall validate all ISO 10303-21 files specified in the part using at least two software tools from different code bases. This validation shall consider both syntactic validation (conformance to the ISO 10303-21 file syntax) and structural validation (conformance to the data specification of an identified EXPRESS schema). The project team shall include the results of this validation in a validation report for the part, which shall also identify the tools used to perform the validation. The project team shall append the validation report to the published quality review report(s).

6.4 Procedure for validation of programming language specifications

If a part includes specifications that use a programming language, the project team shall validate these specifications (or code derived from the specification, if appropriate) using at least two different compilers.

EXAMPLE Implementation methods parts include bindings to programming languages such as C, C++, or Java.

The project team shall include the results of this validation in a validation report for the part, which shall also identify the tools used to perform the validation. The project team shall append the validation report to the published quality review report(s).

6.5 Procedure for validation of ISO 10303 application protocols

The procedure for validation of ISO 10303 application protocols is specified in the Guidelines for the development and approval of STEP application protocols.

6.6 Procedure for validation of ISO 10303 integrated resources and application interpreted constructs

The procedure for validation of ISO 10303 integrated resources and application interpreted constructs is as follows:

a. validation of all EXPRESS schema declarations (see 6.1);
b. review, by experts in the subject area of the data model, for overlap and/or conflict with existing constructs;
c. verification of the uniqueness of EXPRESS schema, data type, function, rule, and procedure names across all SC4 common resources;
d. verification of unique short names using the SC4 Short Name Registry.

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7 Document control

7.1 Project document control

Each SC4 project shall maintain a list of documents as specified in 5.4.4.

The following procedure for documenting changes applies to multiple editions of a standard.

- For second and subsequent editions of a standard, the part editor shall provide a summary of the changes from the previous edition of the standard. This summary shall be included in the Introduction.

The following procedure for documenting changes applies to multiple drafts or versions of a standard or other document developed within a project.

- For any document that the project team produces in two or more successive versions, the team shall maintain records that show how different versions relate to each other. These records shall consist of a brief narrative summarizing the major changes from one version to the next.

EXAMPLE A suitable record describing the relationship between the version of this document submitted for standing document ballot (QC N121) and that distributed for final QC and convener review is as follows:

This version incorporates resolutions to all standing document ballot comments and has been converted from MS-Word to HTML.

- For successive drafts of a standard, the part editor shall provide a list of the major revisions. This list may be included in the "comments to reader" section of the document cover page (see the Supplementary Directives for details of document cover pages), or in the Introduction to the document.

All changes to standards documents that have reached Committee Draft shall be traceable either to a ballot issue, an issue that is documented in the project issues log, or to changes required by internal quality reviews, project leader reviews, convener reviews, or quality audits. By following this requirement projects ensure that they introduce change in a controlled manner.

7.2 Document identification

N-numbers uniquely identify documents within a Subcommittee, Working Group, or Committee. Projects shall not use the same N-number for different versions of a document nor introduce subdivisions of an N-number such as "N123a" or "N123 version 2". For documents that are distributed only within a project, N-numbers are not necessary (although projects are strongly encouraged to apply strict document version control). When a document is distributed on paper or electronically, or is discussed at a recognized ISO meeting, the project leader or part editor shall obtain an N-number from the Working Group convener. Only in exceptional circumstances may documents be distributed as "N???", "Nxxx", etc. If this method of numbering is necessary (for example, if the WG convener cannot be contacted,) then an N-number should be

obtained as soon as possible and the document republished or redistributed with a valid number.

The SC4 Secretariat maintains an index of all SC4 N-numbered documents. This list is published on SOLIS and provides access to all SC4 documents that are available electronically. Conveners of the Working Groups and the Quality Committee maintain indexes of their N-numbered documents and publish them on SOLIS, providing access to all WG and QC documents that are available electronically.

Editor's note This statement is actually false; many of the WG directories on SOLIS lack an up-to-date index of documents.

The indexes maintained by the SC4 Secretariat and by the Working Group and Quality Committees shall include the following information about each N-numbered document:

- for standards documents:
  - the Project Leader;
  - the Part Editor;

  for other SC4 documents
  - the document author(s);
- the document title;
- the document date;
- the document N-number;
- the N-number of the previous revision of the document, if any;
- the N-number of the succeeding revision of the document, if any;
- the format and file name of the source of the document;

NOTE 1 It is not a requirement that document source files are maintained and published (the minumum requirement is for PDF for formatted documents and ASCII[1)] for unformated documents and computer-interpretable specifications).

- the format and file name of any printable version of the document (e.g., PostScript or PDF);
  - all standards documents shall be provided in PDF format at each ballot stage and for final publication by ISO;
  - use of PostScript is limited to legacy documents - where possible, these should be converted to PDF.
- the format and file name of an ASCII (plain text) version of the document;

EXAMPLE EXPRESS schema declarations that are published in computer-interpretable format are ASCII files.

- the location of these files on SOLIS.

NOTE 2 Due to copyright restrictions standards documents at stage 40 (DIS), 50 (FDIS), and 60 (IS, TS, TR, or PAS) are not published in the public area of SOLIS. They are available to standards developers from a password protected private area on SOLIS.

If the index is published on SOLIS, then it shall include links to the source and printable versions of the document, if available.

[1)] The term "ASCII" is used in its colloquial sense here to stand for a number of possible encodings of basic letters, numbers, and symbols.

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8 Process control

The project leader ensures that the development, authoring, and publishing tools used on the project are appropriate to the task, and that any necessary configuration of these tools (for example, style sheets in the case of authoring tools) is undertaken correctly.

The Quality Commitee shall maintain and publish on SOLIS a document with guidelines on selecting and using tools and incorporates such information into its training courses. The Quality Committee shall also support project teams by providing approved style sheets and by encouraging exchange of experiences between projects.

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9 Quality audits

9.1 Project audits

At any stage in its work, an SC4 project may carry out an audit of its own work. A project audit can be used to identify and implement opportunities for process or quality improvement. A project audit may also be useful in circumstances such as the following:

- change in project leader, part editor or key project team members;
- resumption of work on a project after a period of inactivity;
- negative feedback from preliminary industry review of the standard.

The project audit is initiated by the project leader and may be carried out by the project leader, another project team member, or by an external quality expert. Support may also be requested from the Quality Committee; however, the Quality Committee's capability to provide such support depends on the availability of suitable (volunteer) resources. No specific procedures are prescribed for such audits; however, projects are encouraged to apply the procedure specified in 9.2. The project team should document the following results of project audits and keep them as part of the project's quality records:

- recommendations for improvement;
- corrective actions;
- preventive actions;
- implementation of all recommendations and actions.

9.2 QC audits

9.2.1 Triggers for QC audit

The activities of an SC4 project may be subject to QC audit under the following circumstances:

- the project fails to deliver the required documents for initiation of a ballot;
- failure to achieve consensus or approval in any ballot cycle due to quality issues;
- decision by the SC4 Chair and/or Secretariat (in consultation with the project leader and the Quality Committee coordinator) after any ballot;
- a national body requests a quality audit.

The scope of an audit can be the full scope of the project activities, or can be limited by the auditor to particular aspects of the project where quality defects have been observed.

EXAMPLE If the standard is of sufficient quality with respect to editorial requirements (spelling, grammar, layout, presentation, etc.) but contains errors in EXPRESS specifications, then the scope of the audit can be limited to validation of EXPRESS and to the review and approval

procedures that allowed a document with defects to be submitted for ballot.

Audits are scheduled on a "first come first served" basis, taking into account the availability of auditors.

9.2.2 Audit process

Figure 2 below shows an overview of the QC Audit process and the responsible parties.

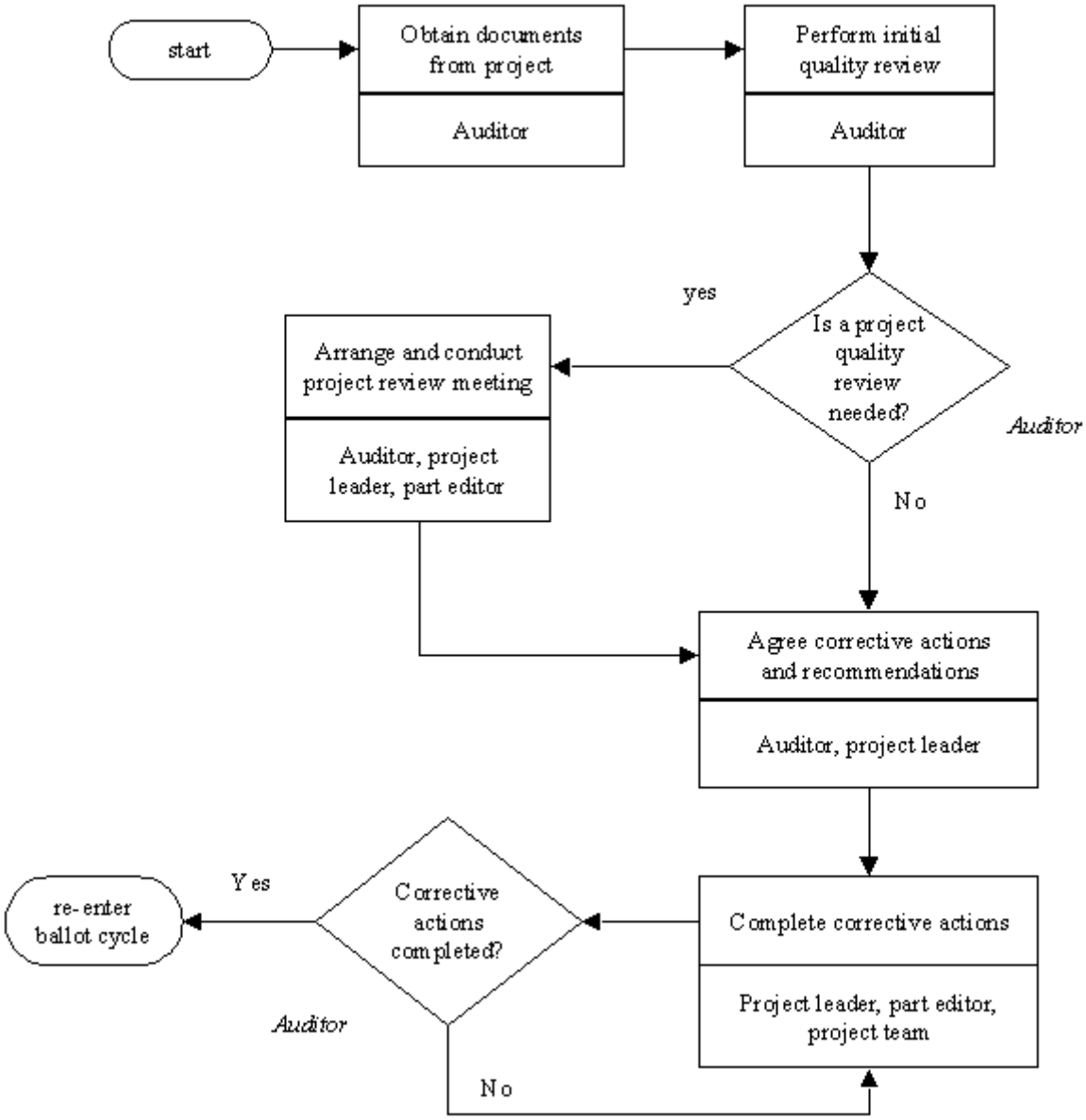

Figure 2 – Audit procedure

9.2.3 Appointment of auditors

When a project requires a QC audit, the Quality Committee coordinator shall appoint an auditor. Auditors are members of the Quality Committee with the following skills, experience, and qualifications:

- familiarity with the ISO 9000 series of standards (or other formal quality standards) and experience of quality audits as described in ISO 9000;
- knowledge and experience of SC4 standardization projects;
- familiarity with the SC4 quality system and with ISO and SC4 procedures.

The appointed auditor shall be acceptable to the project leader. In the event of dispute over the appointment of an auditor, the SC4 Chair (in consultation with the SC4 Secretariat and the PPC) has the authority to

override the QC coordinator’s appointment or the project leader's objections.

9.2.4 Audit procedures

The stages of a QC Audit are as follows (see Figure 2 above).

The auditor reviews the project document log and identifies those documents that are relevant to the scope of the audit. The auditor should directly obtain any documents that are on SOLIS; other documents should be obtained from the project leader.

The auditor reviews the selected documents in the context of the reported quality defects. On the basis of this review the auditor can

a. document the quality audit observations that identify quality defects, proposed corrective actions that address them, preventive actions that help to avoid future quality defects, and any recommendations for quality or process improvement; or
b. request a project quality review meeting to discuss the auditor’s observations.

In case (a) the project leader shall review proposed corrective and preventive actions together with the part editor, project quality representative, and other project team members as necessary. The auditor and the project leader shall agree a schedule for completing all corrective and preventive actions. In case (b) a meeting among the auditor, project leader, project quality representative, and other project team members shall be arranged. If possible, this meeting shall take place during one of the regular meetings of ISO TC184/SC4 and its WGs. Participants in the project quality review shall discuss the identified quality defects and recommended remedies. They shall all agree to corrective and preventive actions and a schedule for their completion.

When the project team has completed all the agreed corrective and preventive actions, all affected documents shall be sent to the auditor for final review. If one or more corrective or preventive actions have not been completed to the auditor's satisfaction, then the auditor shall inform the project leader of the outstanding work to be done, and they shall agree on a revised schedule for completion of the corrective and preventive actions.

If a project repeatedly fails to complete corrective and preventive actions to schedule or to the desired degree of quality, then the auditor shall suspend the audit and shall inform the QC coordinator, the convener of the parent WG, and the SC4 chair. The QC coordinator, the convener of the parent WG, and the SC4 chair shall then make a recommendation regarding the future work of the project to the next SC4 meeting.

EXAMPLE Possible recommendations in this situation include removal of the project leader or other project team members, and cancellation of the project.

Projects shall pay appropriate attention to quality requirements so that this situation never arises.

Once the project team has completed all corrective and preventive actions, the auditor publishes an audit report (as a QC N-numbered document on SOLIS). The project then proceeds to the next phase of developing and balloting. Under no circumstances shall a project be permitted to proceed to ballot if any corrective or preventive action arising from an audit is not complete.

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10 Training

SC4's policy on training is that each project team developing an SC4 standard is fully trained in the methods needed to ensure high quality standards. The project leader for each standard is responsible for implementing this policy within the project. Project team members are responsible for identifying requirements for training necessary to deliver quality standards. The Quality Committee provides guidance and support to project teams and audits compliance with training requirements.

The Project Leader shall ensure that Project Team members have the necessary skills to carry out their tasks.

The Quality Committee supports the Project Leader by the following:

- defining the necessary skills for various roles within the team;
- providing methods to measure an individual's skill level;
- ensuring the availability of training to develop certain necessary skills;
- auditing necessary skills within the Project Team.

The Quality Committee provides an SC4 training program that includes details regarding training requirements and opportunities.

The Quality Committee reserves the right to remove sign-off authority from the project team or project leader, if requests to improve skill levels are not acted upon.

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Annex A
Quality plan template

Standard:	Part:	Stage:	Date:
Project leader	*As confirmed by SC4 resolution; SC4 Secretariat maintains records of affiliation, contact details, etc.*		
Part editor	*As confirmed by SC4 resolution; SC4 Secretariat maintains records of affiliation, contact details, etc.*		
Project quality rep.	*As identified in the project's New Work Item Proposal documentation. Any changes to be notified to the SC4 Secretariat and to the QC coordinator*		
Other project team members	(name)	(role)	
Repeat as necessary	(name)	(role)	
P-member countries participating in the work:	*List countries – at least five*		
Period covered by this quality plan	Dates	Project stage(s) *Minimum is one project stage or ballot cycle; e.g., "from submission of Committee Draft to submission of DIS"*	
Total project resources for this period	(hours)		
Project resources allocated to quality for this period	(hours)		
Project quality tasks to be undertaken during this period	(task)	(person responsible)	
Repeat as necessary	(task)	(person responsible)	
Training requirements for this period	(training course)	(person to receive training)	
Repeat as necessary	(training course)	(person to receive training)	

NOTE This template will be made available in electronic form, including via the World Wide Web for on-line completion.

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Annex B
Quality report requirements

B.1 List of project participants

A list of project participants, including their affiliations and contact details (see 5.4.4)

B.2 Project document log

The project document log should include all the information required for indexes of Working Group documents (see 7.2).

B.3 Project issues log

The project issues log should record the following information for each issue:

- issue number;
- date submitted;
- submitter;
- version of the part document against which the issue was raised;
- clause/subclause;
- paragraph/figure/table;
- type of comment - general/technical/editorial;
- comment;
- proposed change;
- observations of the project (actual resolution);
- status - open/closed;
- response - accept/reject/defer/transfer;
- date incorporated.

This collection of fields represents the union of the information required by ISO in the ballots of DIS documents and that required by the SEDS process.

B.4 Record of industry reviews

The project team shall record the following information for each industry review conducted:

- date of review;
- venue;
- participants (name and affiliation);
- version of the part document reviewed;
- reference to the minutes and/or notes of the review meeting;
- reference to the version of the project issues log in which issues arising from the review are documented.

B.5 Internal reviews

The project team shall record the following information for each internal review:

- date of review;
- name(s) of person(s) who conducted the review;
- reference(s) to completed checklist(s);
- reference(s) to validation or verification report(s).

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